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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,008	07/31/2003	Robert E. Richard	02-263	9358

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EXAMINER	
KENNEDY, SHARON E	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,008	RICHARD ET AL.	
	Examiner	Art Unit	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, and 4-27* is/are pending in the application.

4a) Of the above claim(s) *24-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains claims 24-27 drawn to an invention nonelected with traverse in the reply filed on 11/13/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 6, 7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zaffaroni et al., US 3,896,819. Regarding claim 1, Zaffaroni discloses a silicone-carbonate copolymer in column 13, lines 29-30, which anticipates applicant's claimed polymeric release region comprising a silicone copolymer. Applicant asserts that this claim would distinguishes over Zaffaroni in view that the examiner had not rejected claim 2 previously in view of Zaffaroni. This is an incorrect assumption. The examiner is not required to apply all possible prior art rejections in view of all the prior art cited or

relied upon. This is due to time constraints. Applicant is expected to read the references and make their own determinations. Regarding claims 5, 6, see Zaffaroni column 7, lines 59-67. Regarding claim 7, note column 18, lines 55+.

Claims 1, 4, 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bruck, US 4,559,054. Regarding claim 1, see especially column 2, lines 24-45, disclosing all of the claimed subject matter. Regarding the coating process, note column 5, lines 5+. Regarding claim 18, broadly interpreted, the limitation is anticipated by the Bruck disclosure at column 4, lines 35+.

Claims 1, 9-19, 21-23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lee, US 4,833,218. Note especially column 11, lines 35-37, indicating that the copolymers are useful for forming membranes to control delivery of a drug from a reservoir. Regarding the claimed transition temperatures, the embodiments are considered to be inherent from the Lee disclosure in view that the identical preferred polymers are disclosed. Lee discloses (A) the polydiorganosiloxane block copolymers having polyalkyleneoxy segments (anticipating applicant's claimed "supplemental polymer" of claim 18 or "triblock copolymer" of claim 23) and (B) a water insoluble aliphatically unsaturated organic monomer such as methyl methacrylate. See the abstract, column 10, lines 1+, etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni et al., '819. Applicant cites an elongation at break of at least 25%. Zaffaroni does not disclose an elongation at break, however, applicant's claimed 25% is a modest amount. In view that the device is an intrauterine device, an assumption can be made that the device has a reasonable elongation at break in view that the device must be dramatically manipulated/compressed for insertion through the cervix into the uterus. Regarding claim 20, the sterilization of an implant is inherent. The method varies from device to device, but radiation sterilization is a common method.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

The prior art made of record and/or relied upon is considered pertinent to applicant's disclosure. Applicant should note that the examiner is not required to apply all possible prior art rejections, even with the applied references above. Additional claims may be anticipated or obvious in view of the above applied references, but have not been analyzed due to time constraints. The examiner is only required to reject each unpatentable claim one time. Applicant is expected to read all the references cited by the examiner, particularly those applied, and make their own determinations as to anticipation or obviousness for each claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sharon E. Kennedy/
Sharon E. Kennedy
Primary Examiner
Art Unit 1615